REMARKS

Status of Claims

Claims 1-38 and 61 are pending in the application. Claims 1-38 and 61 are rejected. With this Amendment, claims 1, 23-27, 33, 37, 38, and 61 have been amended, and claim 22 has been canceled without prejudice.

Rejection Under 35 U.S.C. §112

Claims 1-38 and 61 were rejected under § 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, "the claims recite determining the degree of perfusion when flow is substantially below normal and PCO2 is substantially above normal and/or the pH is substantially below normal," but such a limitation is not supported by the specification as filed. However, the Examiner went on to state that "[t]he specification teaches that the conditions are indicative of perfusion failure, but not that the degree of perfusion is measured."

Applicants respectfully disagree with the Examiner's position that there is no support in the specification as filed for determining the degree of perfusion when measured blood flow is substantially lower than a normal blood flow and the measured PCO2 is substantially above normal and/or the pH is substantially below normal. Therefore, Applicants believe the rejection under § 112, first paragraph, should be withdrawn. However, in order to advance prosecution, Applicants have amended claim 1 to recite "wherein a measured blood flow in the adjacent tissue that is substantially lower than a normal blood flow and a PCO2 measurement that is substantially higher than a normal PCO2 measurement is indicative of the degree of systemic perfusion of the patient." This amendment is consistent with the Examiner's statement above regarding what he believes is supported by the specification. Similar amendments were also made to claims 33, 37, 38, and 61. In view of the claim amendments, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 102(b) and Alternatively Under § 103(a)

The Examiner rejected claims 1-29, 33-35, and 38 under 35 U.S.C. § 102(b) as being anticipated by Rosenberg et al., U.S. Patent Number 4,538,618 ("Rosenberg"), or in the alternative, under 103(a) as being unpatentable over Rosenberg. In rejecting claims 1-29, 33-35, and 38, the Examiner stated that "Rosenberg has a blood flow sensor, i.e., fiber 16, located in a measuring head 2 and an indicator 36, for indicating the blood flow measurement" and that "[t]he device further includes a PCO2 sensor (see column 5, line 55)." It is the Examiner's position "that there would also be an indicator for indicating the PCO2 measurement, given that the reference provides an indicator for all of the other measured values." Alternatively, the Examiner "takes official notice that it is well known to display measurement values in medical devices, to inform the user and/or physician of the patient's condition." The Examiner went on to state that "the degree of systemic perfusion, i.e. the blood flow, is displayed all the time including when the recited conditions are met."

In response, independent claim 1 has been amended to recite "[a] device for assessing the degree of systemic perfusion in a patient . . . comprising . . . blood-flow sensor means . . . and a positioning means for locating or maintaining the blood-flow sensor means at a position in the upper respiratory/digestive tract, the positioning means comprising a holder member having a holder passage extending within at least a portion of the holder member and structured to receive the blood-flow sensor means, a portion of the blood-flow sensor means extending outside of the holder passage and engageable with the position in the upper respiratory/digestive tract." Rosenberg does not disclose, teach, or suggest a device for assessing the degree of systemic perfusion that includes a holder member having a holder passage extending therein and structured to receive a blood-flow sensor means, the blood-flow sensor means being engageable with a mucosal surface in the upper respiratory/digestive tract, as now recited by claim 1. In addition, Rosenberg does not disclose, teach, or suggest any element having similar structure to the positioning means now recited in claim 1 or that is capable of performing a similar function. Because Rosenberg fails to disclose, teach, or suggest each element of amended independent claim 1, the rejection of claim 1 under § 102(b) and/or § 103(a) should be withdrawn.

With this Amendment, the limitations from dependent claim 22 have been incorporated into independent claim 1, and claim 22 has been canceled without prejudice. Claims 2-21 and 23-32 depend from independent claim 1. As such, these claims are allowable with their independent base claim. In addition, it is respectfully submitted that the combinations of features recited in claims 2-21 and 23-32 are patentable on their own merits, although this does not need to be specifically addressed herein since any claim depending from a patentable independent claim is also patentable.

In rejecting claims 33-35, the Examiner stated that "the phrase 'shaped to fit' is being interpreted as meaning only capable of fitting," and the Examiner suggested that Applicants recite "that the sensor holder has a shape corresponding to the shape of the area under the tongue or use similar language." In response, independent claim 33 has been amended consistent with the Examiner's suggestion to recite "[a] device for assessing the degree of systemic perfusion in a patient, the device comprising . . . a sensor holder with an inner portion and an outer portion, said inner portion having a shape generally corresponding to the shape of the area under the patient's tongue . . .." In view of the amendment to claim 33, Applicants respectfully request that the rejection of claim 33 be withdrawn.

Claims 34-36 depend from independent claim 33. As such, these claims are allowable with their independent base claim. In addition, it is respectfully submitted that the combinations of features recited in claims 34-36 are patentable on their own merits, although this does not need to be specifically addressed herein since any claim depending from a patentable independent claim is also patentable.

Claim 38 has been amended to recite "[a] device for assessing the degree of systemic perfusion in a patient . . . comprising . . . a blood-flow sensor . . . an indicating means operably connected to the sensor means for indicating the measured blood flow . . . and a sensor holder adapted to hold the blood-flow sensor adjacent the mucosal surface in the upper respiratory/digestive tract, the sensor holder comprising a flexible member having a sensor holder passage with the blood-flow sensor disposed therein, at least a portion of the blood-flow sensor being exposed from within the sensor holder passage and structured to engage the

mucosal surface." Rosenberg does not disclose, teach, or suggest a device for assessing the degree of systemic perfusion that includes a sensor holder having a flexible member with a sensor holder passage therein as now recited by claim 38. In addition, Rosenberg does not disclose, teach, or suggest any element having similar structure to the sensor holder now recited in claim 38 or that is capable of performing a similar function. Because Rosenberg fails to disclose, teach, or suggest each element of amended independent claim 38, Applicants respectfully request that the rejection of claim 38 be withdrawn.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected claim 30 under 35 U.S.C. § 103(a) as being unpatentable over Rosenberg in view of Riccitelli et al., U.S. Patent Number 5,166,990 ("Riccitelli"). According to the Examiner, Riccitelli "further teaches that it is known to monitor pH and PCO2 in the same intravascular measuring device" and therefore, that "it would have been obvious to modify Rosenberg to include a pH sensor, to provide a more complete picture of the patient's condition." Applicants believe they patentably distinguish over the primary reference, and thus neither Rosenberg alone or in combination with Riccitelli disclose, teach, or suggest a "positioning means comprising a holder member having a holder passage extending within at least a portion of the holder member and structured to receive the blood-flow sensor means, a portion of the blood-flow sensor means extending outside of the holder passage and engageable with the position in the upper respiratory/digestive tract."

The Examiner rejected claims 31 and 32 under 35 U.S.C. § 103(a) as being unpatentable over Rosenberg in view of Boggett et al., WO 98/20794 ("Boggett"). According to the Examiner, Boggett "teaches that in a microvascular monitoring device like that of Rosenberg, it is known to monitor the rate of change of blood flow. As such, it would have been obvious to modify Rosenberg to include a rate of change of flow determining device, to provide a more complete picture of the patient's condition." Applicants believe they patentably distinguish over the primary reference, and thus neither Rosenberg alone or in combination with Boggett disclose, teach, or suggest a "positioning means comprising a holder member having a holder passage extending within at least a portion of the holder member and structured to receive the blood-flow

sensor means, a portion of the blood-flow sensor means extending outside of the holder passage and engageable with the position in the upper respiratory/digestive tract."

The Examiner rejected claims 33-37 under 35 U.S.C. § 103(a) as being unpatentable over Millar, U.S. Patent Number 4,966,148 ("Millar"). According to the Examiner, "Millar shows a device including a blood flow sensor and a sensor holder 20 that is capable of holding the device in place." The Examiner admitted that Millar does not disclose an indicator, but went on to take official notice that "it is well known to display measurement values in medical devices, to inform the user and/or physician of the patient's condition." In the Examiner's opinion, "the degree of systemic perfusion could then be deduced from the indicator." With respect to claim 37, the Examiner argued that "Millar teaches a device with a flow sensor and a pH sensor (column 2, lines 28-49)," and it once again would have been obvious to include the indicator as part of the device as previously discussed. Applicants traverse the rejection. Millar does not disclose, teach, or suggest "[a] device for assessing the degree of systemic perfusion in a patient, the device comprising . . . a sensor holder with an inner portion and an outer portion, said inner portion having a shape generally corresponding to the shape of the area under the patient's tongue . . ." as now recited by independent claim 33. Claims 34-36 depend from independent claim 33, and should be allowable therewith. Millar also does not disclose, teach, or suggest "[a] device for assessing the degree of systemic perfusion in a patient . . . comprising . . . a blood-flow sensor . . a pH sensor . . . and a sensor holder having a holder passage extending within at least a portion of the sensor holder and structured to receive the blood-flow sensor, at least a portion of the blood-flow sensor exposed from within the holder passage and engageable with the mucosal surface," as now recited by independent claim 37. What Millar discloses, in fact, is a coupling mechanism 20 depending from the body 14 and "adapted for slidably engaging a guidewire, such that with the guidewire positioned in a biological vessel and the coupling mechanism engaging the guidewire, the body is slidable along the length of the guidewire in the vessel." (Col. 4, lines 42-47.) Thus, the coupling mechanism in Millar is not a sensor holder as recited in the claims, but rather a device for slidably receiving a guidewire that is inserted into a biological vessel. In view of the amendments to claims 33 and 37, Applicants respectfully request that the rejection of claims 33 and 37 be withdrawn.

The Examiner rejected claim 61 under 35 U.S.C. § 103(a) as being unpatentable over Rosenberg in view of Riccitelli. According to the Examiner, Riccitelli "further teaches that it is known to monitor pH and PCO2 in the same intravascular measuring device" and therefore, that "it would have been obvious to modify Rosenberg to include a pH sensor, to provide a more complete picture of the patient's condition." Applicants traverse the rejection. The combination of Rosenberg and Riccitelli does not disclose, teach, or suggest "[a] device for assessing the degree of systemic perfusion in a patient . . . comprising . . . a blood-flow sensor . . . a pH sensor . . . a PCO2 sensor . . . and a positioning means for positioning the blood-flow sensor adjacent the mucosal surface, the positioning means comprising a sensor holder having a holder passage extending within at least a portion of the sensor holder, wherein the blood-flow sensor is located within the holder passage, at least a portion of the blood-flow sensor being exposed outside the sensor holder and structured to engage the mucosal surface." In view of the amendment to claim 61, Applicants respectfully request that the rejection of claim 61 be withdrawn.

Conclusion

Applicants respectfully submit that with the arguments and amendments presented herein all pending claims are allowable over the art of record, for at least the reasons discussed above, and respectfully request that a Notice of Allowance with respect to all pending claims be issued in this case.

If the Examiner believes that a teleconference would be of further value in expediting the allowance of the pending claims, the undersigned can be reached at the telephone number listed below.

It is believed that no petition or payment for extension of fees is due. If, however, it is believed that any additional fees are necessary, the Commissioner is hereby authorized to charge or credit any such fees or overpayment to Deposit Account No. 50-1901 (Reference 11242-320).

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Respectfully submitted,

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